

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

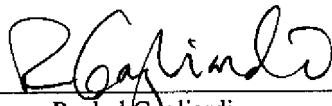
Appellant: THOMAS W. DAVISON Confirmation No.: 7935
Serial No.: 10/689,487 Examiner: Nicholas W. Woodall
Filing Date: OCTOBER 20, 2003 Group Art Unit: 3733
Docket No.: 1291.1134103 Customer No.: 28075
Title: METHOD OF SECURING VERTEBRAE

APPEAL BRIEF

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Rachel Gagliardi

6-9-08

Date

Pursuant to 37 C.F.R. § 41.37, Appellants hereby submit this Appeal Brief in furtherance of the Notice of Appeal filed on March 26, 2008 and of the Notice of Panel Decision from Pre-Appeal Review dated May 8, 2008. Appellants authorize the fee prescribed by 37 C.F.R. § 41.20(b)(2) in the amount of \$510.00 to be charged to Deposit Account No. 50-0413. Permission is hereby granted to charge or credit Deposit Account No. 50-0413 for any errors in fee calculation.

Application Serial No. 10/972,987
Appeal Brief

TABLE OF CONTENTS

I.	REAL PARTY IN INTEREST.....	3
II.	RELATED APPEALS AND INTERFERENCES	3
III.	STATUS OF CLAIMS.....	3
IV.	STATUS OF AMENDMENTS.....	3
V.	SUMMARY OF CLAIMED SUBJECT MATTER.....	3
VI.	GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL	6
VII.	ARGUMENT.....	6
	A. Claims 18-23, 25-27, 30-36, 38-41, and 46-48 are patentable under 35 U.S.C. § 103(a) over Foley (US 5,792,044) in view of Ash (WO 83/03189) and Zdeblick (US 6,206,922).	6
	i. The Examiner has misinterpreted the claims.....	6
	ii. Claims 18, 27, 33.....	7
	B. Conclusion.....	15
VIII.	CLAIMS APPENDIX	16
IX.	EVIDENCE APPENDIX	20
X.	RELATED PROCEEDINGS APPENDIX.....	21

Application Serial No. 10/972,987
Appeal Brief

I. REAL PARTY IN INTEREST

The real party in interest is Zimmer Spine, Inc., a corporation organized and existing under and by virtue of the laws of Delaware, and having its principal offices at 7375 Bush Lake Road, Minneapolis, MN 55439, USA. An assignment from the inventor, Thomas W. Davison, conveying all right, title and interest in the invention to Endius, Inc., has been recorded at Reel 013600, Frame 0827. A Certificate of Merger merging Endius, Inc. into Zimmer Spine, Inc. was filed on March 28, 2008. A copy of the merger documents is attached.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

III. STATUS OF CLAIMS

Claims 18-23, 25-27, 30-36, 38-41 and 46-48 stand finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Foley (US 5,792,044) in view of Ash (WO 83/03189) and Zdeblick (US 6,206,922). All pending claims, namely claims 18-23, 25-27, 30-36, 38-41 and 46-48, are being appealed.

IV. STATUS OF AMENDMENTS

No Amendment-After-Final was filed.

V. SUMMARY OF CLAIMED SUBJECT MATTER¹

The invention relates generally to surgical systems and assemblies that include an access device for minimally invasive surgery. In particular, the invention relates to systems and devices that provide access to a surgical location, e.g. adjacent a spine, and provide visualization of at least two fasteners fixed to two adjacent vertebrae. More particularly, the invention relates to a system including at least two vertebral fasteners, a fixation element adapted to engage the fasteners, and an access device actuatable between a first configuration sized for insertion into

¹ The references to the specification and drawings provided herein are only illustrative and not limiting in any way.

Application Serial No. 10/972,987
Appeal Brief

the patient and a second configuration where the cross-sectional area at a first location is greater than the cross-sectional area at a second location, and the first location is distal to the second location (see, for example, specification at paragraphs 0048-0049, 0055, 0092, 0098-0100 as published, and FIGS. 1, 5, 24-29).

Turning now to the claims, where independent claim 18 recites a system for performing a fixation procedure at a spinal location within a patient, the system including at least two fasteners adapted to be fixed to two adjacent vertebrae (see specification at, for example paragraph 0092 as published and FIG. 25, reference number 624), an elongate body having a proximal end and a distal end and defining a length between the proximal and distal ends such that the proximal end can be positioned outside the patient and the distal end can be positioned inside the patient adjacent the spinal location, the elongate body including a passage extending between the proximal and distal ends sized to permit passage of the at least two fasteners therethrough (see specification at, for example paragraphs 0048-0049 as published and FIGS. 1, 5, reference number 10), and a fixation element sized to pass through the passage of the elongate body and configured to engage the at least two fasteners (see specification at, for example paragraphs 0098-0100 as published and FIGS. 25, 27, 29, reference numbers 651, 651a, 658a). The elongate body is actuatable between a first configuration sized for insertion into the patient (see specification at, for example paragraph 0048 as published and FIG. 2) and a second configuration wherein the cross- sectional area of the passage at a first location is greater than the cross-sectional area of the passage at a second location, where the first location is distal to the second location, and the cross-sectional area of the passage at said first location is sized to permit visualization of two fasteners fixed to two adjacent vertebrae (see specification at, for example paragraph 0049 as published and FIG. 1).

Dependent claim 20 recites the system of claim 18, wherein the distal portion of the elongate body is expandable (see specification at, for example paragraph 0048 as published and FIG. 1, reference number 40).

Independent claim 27 recites a system for performing a fixation procedure at or near the spine of a patient. The system includes an access device adapted to define a passage from a

Application Serial No. 10/972,987
Appeal Brief

location outside of the patient to a location at or near the spine of the patient (see specification at, for example, paragraphs 0054-0055 and FIG. 5, reference number 10). The access device is at least partially actuatable between a first configuration (see, for example, FIG. 2) and a second configuration (see, for example, FIG. 1). The passage of the access device in the second configuration has a cross-sectional area at a first location (see specification at, for example paragraph 0049 as published, and FIG. 1, reference number 62) that is greater than the cross-sectional area of said passage at a second location (see specification at, for example paragraph 0049 as published and FIG. 1, reference number 60), wherein the first location is distal to the second location. The system also includes a vertebral fixation assembly (see specification at, for example paragraph 0092 as published and FIG. 25, reference number 620) configured to fix two adjacent vertebrae. The vertebral fixation assembly is adapted to be delivered through the passage of the access device, and the vertebral fixation assembly includes a plurality of vertebral screws (see specification at, for example paragraph 0092 as published and FIG. 25, reference number 624) and a fastener (see specification at, for example paragraph 0098 as published and FIG. 25, reference number 651) adapted to engage each of the vertebral screws. The cross-sectional area of the access device at the first location is sized to permit visualization of two or more screws fixed to at least two adjacent vertebrae (see specification at, for example paragraphs 0049 and 0092 as published and FIG. 25, reference number 624).

Dependent claim 32 recites the system of claim 27, wherein the access device includes a distal portion that is expandable (see specification at, for example paragraph 0048 as published and FIG. 1, reference number 40).

Independent claim 33 recites a system for performing a fixation procedure at a spinal location within a patient that includes an access device (see specification at, for example paragraph 0040 as published and FIG. 1, reference number 10), at least two threaded fasteners (see specification at, for example paragraph 0092 as published and FIG. 25, reference number 624), and a fixation element sized for delivery through a passage of the access device (see specification at, for example paragraph 0098 as published and FIG. 26, reference number 650). The access device has a proximal end and a distal end and a length defined between the proximal

Application Serial No. 10/972,987
Appeal Brief

and distal ends such that the proximal end can be positioned outside the patient and the distal end can be positioned inside the patient adjacent the spinal location (see specification at, for example paragraphs 0054-0055 as published and FIG. 5, reference number 10). The access device includes a passage extending there through (see specification at, for example paragraph 0040 as published and FIG. 1, reference number 16). The access device is expandable from a first configuration (see FIG. 2) to a second configuration (see FIG. 1). The passage of the access device in the second configuration has a cross-sectional area at the distal end of the device (see specification at, for example paragraph 0049 as published, and FIG. 1, reference number 62) that is greater than a cross-sectional area at the proximal end of the device (see specification at, for example paragraph 0049 as published and FIG. 1, reference number 60), and the passage is sized for delivery of instruments to perform the procedure at the spinal location. The threaded fasteners are sized for delivery through the passage at least when the access device is in its second configuration (see specification at, for example paragraph 0092 as published). The fasteners are configured to be fixed to adjacent vertebrae, and the cross-sectional area at the distal end of the access device in the second configuration is sized to permit visualization of the at least two threaded fasteners fixed to at least two adjacent vertebrae (see specification at, for example paragraphs 0049 and 0092 as published and FIG. 25, reference number 624).

VI. GROUND OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether claims 18-23, 25-27, 30-36, 38-41 and 46-48 are unpatentable under 35 U.S.C. § 103(a) over Foley (US 5,792,044) in view of Ash (WO 83/03189) and Zdeblick (US 6,206,922).

VII. ARGUMENT

A. Claims 18-23, 25-27, 30-36, 38-41 and 46-48 are patentable under 35 U.S.C. § 103(a) over Foley (US 5,792,044) in view of Ash (WO 83/03189) and Zdeblick (US 6,206,922).

i. The Examiner has misinterpreted the claims

MPEP 2143.03 states, “All words in a claim must be considered in judging the

Application Serial No. 10/972,987
Appeal Brief

patentability of that claim against the prior art.’ *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).” The Examiner appears to have either misinterpreted or ignored the structure of the fixation element or fastener as recited in the claims. Independent claim 18 recites, in part, “a fixation element sized to pass through the passage of the elongate body and configured to engage the at least two fasteners”. Emphasis added. The fixation element as claimed has a structure such that the fixation element can engage the two fasteners. Independent claim 27 recites, in part, “a fastener adapted to engage each of the vertebral screws”. Emphasis added. The fastener is structured such that it can engage the vertebral screws.

The Examiner appears to have either misinterpreted or ignored these structures. In the Final Office action mailed December 26, 2007, the Examiner acknowledged that Foley fails to teach a fixation element, but asserts, “Zdeblick teaches a system comprising a fixation element capable of being passed through the passage of an elongate element in order to fuse to adjacent vertebrae.” Emphasis added; see sentence bridging pages 2-3. The Examiner continues with a statement that one of ordinary skill in the art would have been motivated to combine Foley, Ash, and Zdeblick “in order to provide viewing and operation room and to fuse two adjacent vertebrae.” Emphasis added; see lines 6-7 on page 3. While Zdeblick does appear to teach implants for fusing adjacent vertebrae, the reference does not appear to teach a fixation element configured to engage two fasteners, as is recited in claim 18, or a fastener adapted to engage vertebral screws, as recited in claim 27. Zdeblick’s teaching of an implant for fusing vertebrae appears to be irrelevant because the claimed system does not recite implants for fusing vertebrae, but rather a fixation element configured to engage two fasteners (claim 18) or a fastener adapted to engage vertebral screws (claim 27). The Examiner has failed to address these elements of the claims.

ii. Claims 18, 27, 33

The Examiner’s reasons for combining Foley, Ash, and Zdeblick are contradicted by the references themselves. The Examiner asserts that it would have been obvious to manufacture the device of Foley where the elongate body has an expandable distal end in view of Ash and further comprising a fixation element with at least two fasteners capable of being passed through the

Application Serial No. 10/972,987
Appeal Brief

passage of an elongate element in view of Zdeblick "in order to provide viewing and operation room and to fuse two adjacent vertebrae." See page 3, lines 2-7 of the final Office Action. It appears that Foley already teaches a system which provides viewing and operation room to fuse two adjacent vertebrae, thus there is no motivation or reason to modify Foley as asserted by the Examiner. Foley teaches:

as depicted in FIG. 1, a device 10 is provided for use in percutaneous surgery which includes an elongated cannula 20 having a first inner diameter D_1 and an outer diameter D_0 sized for percutaneous introduction into a patient. The cannula 20 also includes a distal working end 21 and an opposite proximal end 22. The cannula defines a working channel 25 between the ends 21, 22 having a second diameter d_2 equal to the first inner diameter D_1 sized for receiving a tool therethrough.

Emphasis added; see column 5, lines 37-46 and FIG. 1. Foley also teaches:

The insertion of vertebral fixation elements can also be accomplished through the device 10. In this type of procedure, an incision can be made in the skin posterior to the location of the vertebra at which the fixation element is to be implanted. Implementing the steps shown in FIG. 10, the cannula 20 can be positioned through the incision and tissue directly above the particular location on the vertebra to be instrumented. With the optics extending through the working channel, an insertion tool holding the vertebral fixation element can be projected through the cannula 20 and manipulated at the vertebra. In one specific embodiment, the fixation element can be a bone screw. The working channel 25 has a diameter that is large enough to accept most bone screws and their associated insertion tools.

...

The device 10 can also be used to prepare a site for fusion of two adjacent vertebrae, and for implantation of a fusion device or material.

...

A fusion device, such as a bone dowel, a push-in implant or a threaded implant can then be advanced through the working channel of device 10 and into the prepared bore at the subject disc space. In some instances, the preparatory steps involve preparing the vertebral endplates by reducing the endplates to bleeding bone. In this instance, some aspiration and irrigation may be beneficial. All of these procedures can be conducted by tools and instruments extending through the working channel cannula 20 and under direct vision from the viewing element 50.

Application Serial No. 10/972,987
Appeal Brief

Emphasis added; see column 15, lines 3-15, 35-37 and 57-67. Foley thus appears to teach a system for insertion of either vertebral fixation elements, such as bone screws, or fusion implants through the fixed diameter device 10. Foley also appear to teach the insertion of the screws or implants as being done under direct vision from a viewing element. Zdeblick appears to teach insertion of fusion device 10 through a fixed diameter outer sleeve 76. See column 11, lines 3-16 and FIG. 11c. Both Foley and Zdeblick appear to teach insertion of fusion devices through fixed diameter devices, thus there is no motivation for one of ordinary skill in the art to modify Foley and/or Zdeblick to use a device with an expandable distal end, as asserted by the Examiner. The Examiner's reasons for combining Foley and Zdeblick with Ash is "to provide viewing and operation room and to fuse two adjacent vertebrae." However, as discussed above, Foley and Zdeblick already appear to teach devices that provide viewing and operation room to fuse adjacent vertebrae. In view of the specific teachings of Foley and Zdeblick, the motivation to combine their teachings with Ash appears to be (1) because their combination is within the skill of the ordinary artisan; (2) found in Appellant's specification; or (3) merely because the references could be combined. All of these possible motivations to combine Foley, Zdeblick and Ash are improper.

MPEP 2143.01 states:

A statement that modifications of the prior art to meet the claimed invention would have been "well within the ordinary skill of the art at the time the claimed invention was made" because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993). ***">[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396 quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006).<

Appellants submit that the Examiner has failed to provide any objective reason with rational underpinning to combine the teachings of Foley, Zdeblick and Ash. As discussed above, Foley

Application Serial No. 10/972,987
Appeal Brief

and Zdeblick already appear to teach providing viewing and operation room and to fuse two adjacent vertebrae, thus the Examiner's stated reason for combining the teachings is not supported by the references and appears to be a mere conclusion, which is improper.

MPEP 2143.01 III states:

The mere fact that references can be combined or modified does not render the resultant combination obvious unless **>the results would have been predictable to one of ordinary skill in the art. *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1396 (2007)

Appellants submit that combining Foley, Zdeblick and Ash would not have provided predictable results to one of ordinary skill in the art. As discussed above, Foley and Zdeblick teach devices for implanting fusion devices between vertebrae through fixed diameter devices. Ash teaches a surgical device for the visual inspection of tissue within a patient, for performing medical procedures such as biopsy or tissue sample collection, and for tissue ablation by laser irradiation. There is no indication that the tissue sample collection device of Ash would function to allow passage of the implant and implant insertion devices of Foley and/or Zdeblick. In particular, Ash teach a relatively large viewing conduit 24 coupled with internal conduit 34 and relatively small access channel 88 containing biopsy sampling means 90. See page 5, lines 32-35, page 9, line 24 through page 10, line 1, and Figs. 1-3.

While Ash teach the device can be used for spinal disc surgery, Ash only teach using the device with laser irradiation to remove a portion of a spinal disc, and using the levers as the grasping instrument to remove the disc portion. See page 13, lines 8-24. Appellant submits that there is no suggestion or indication that the structure of Ash could be used for insertion of the implants of Foley and/or Zdeblick, as suggested by the Examiner, and/or screws and fixation devices, as recited in the claims. As discussed above, Ash appears to teach a device with a relatively large viewing channel 24, 34 and comparatively small instrument insertion access channel 88. In view of the structure of the device of Ash, there is no indication that the device could predictably be used for the insertion of two fasteners and a fixation element configured to engage the two fasteners (claim 18), a plurality of vertebral screws and a fastener adapted to

Application Serial No. 10/972,987
Appeal Brief

engage the screws (claim 27), or at least two threaded fasteners and a fixation element (claim 33). It would appear that significant modification of the device of Ash would be necessary in order to use it to insert the implants of Foley and Zdeblick, as asserted by the Examiner. Because Foley and Zdeblick already teach insertion devices for their implants, there is no motivation for such modifications to Ash, and the teaching of the apparently unexpandable insertion devices of Foley and Zdeblick appear to teach away from such modifications to Ash.

Further, even if one were to combine Foley, Zdeblick, and Ash as suggested by the Examiner, one would not arrive at the claimed system. As discussed above, neither Foley nor Zdeblick appear to teach a system having at least two fasteners and a fixation element configured to engage the fasteners (claim 18) or a plurality of vertebral screws and a fastener adapted to engage each of the vertebral screws (claim 27). Additionally, neither reference appears to teach at least two threaded fasteners and a fixation element as recited in independent claim 33. At best, a combination of Foley, Zdeblick, and Ash would appear to result in a system including a fusion implant, a fixed diameter insertion device, and a tissue sampling device. The combination of Foley, Zdeblick, and Ash does not teach or suggest the elements of the claims and thus does not render obvious the system of independent claims 18, 27, and 33.

Additionally independent claim 18 recites, in part:

wherein the elongate body is actuatable between a first configuration sized for insertion into the patient and a second configuration wherein the cross-sectional area of said passage at a first location is greater than the cross-sectional area of said passage at a second location, wherein the first location is distal to the second location; wherein the cross-sectional area of said passage at said first location is sized to permit visualization of two fasteners fixed to two adjacent vertebrae.

Emphasis added. Independent claims 27 and 33 recite similar cross-sectional areas of the passage. None of Foley, Ash or Zdeblick appears to teach or suggest such a structure. The Examiner acknowledges that Foley fails to disclose a system comprising an elongate body that is expandable at the distal end at a first location. Ash is cited as teaching a device having an elongated body expandable at the distal end to provide viewing and operation room. The Examiner asserts that it would have been obvious to manufacture the device of Foley with an

Application Serial No. 10/972,987
Appeal Brief

expandable distal end in view of Ash and further to add a fixation element with at least two fasteners capable of being passed through the passage of the elongate element in view of Zdeblick to provide viewing and operation room and to fuse two adjacent vertebrae.

The Examiner has provided no articulated reason for why one of skill in the art would have been motivated to modify the percutaneous surgical devices of Foley to have an expandable distal end. Foley specifically teaches percutaneous devices providing both the desired viewing element and working channel for inserting the required instruments. See column 3, lines 24-65 and FIG. 1. The Examiner asserts that the modification of Foley in view of Ash would be done “to provide viewing and operation room”. Foley already provides a device that provides viewing and operation room. Foley specifically teach:

According to the methods of this invention, spinal and other surgeries can be performed percutaneously with direct visualization without the requirement for a fluid-maintained working space. In another aspect of the inventive surgical techniques, all steps of a surgical procedure are conducted under direct vision through a single working channel cannula. An optical scope or viewing device is moved within the working channel and throughout the working space from a variety of angles and orientations to provide a clear view of the operative steps.

Emphasis added; see column 4, lines 9-18. Foley teaches a system as providing a device that allows all steps of a surgical procedure to be performed through a single working channel cannula, thus Foley actually appears to teach away from modifications to their system using Ash. The Examiner’s asserted motive of modifying Foley “to provide viewing and operation room” is directly contradicted by Foley’s teaching that their system allows surgeries to be “performed percutaneously with direct visualization”; see above quote. Foley teaches a system allowing an optical scope or viewing device to be “moved within the working channel and throughout the working space from a variety of angles and orientations to provide a clear view of the operative steps.” See above quote. Appellants submit that Foley teaches away from modifying their system to achieve the Examiner’s asserted advantage because Foley already provides such advantages. The Examiner’s asserted motivation for modifying Foley in view of Ash thus lacks any rational underpinning. The only motivation or rational reasoning for modifying Foley in view of Ash comes from Appellants’ specification, which is improper. In view of Foley’s

Application Serial No. 10/972,987
Appeal Brief

specific teachings of the advantages of their percutaneous system, which provides viewing and operation room in a single, unexpandable, device, Appellants submit that there is no motivation for one of ordinary skill in the art to modify the device in view of Ash.

Zdeblick appears to teach an unexpandable sleeve 76 that functions as a fixed diameter working channel through which a fusion device 10 is implanted using an implant driver 50. See column 11, lines 8-17 and FIG. 11c. Thus both Foley and Zdeblick appear to teach fixed diameter devices for inserting other devices or instruments to a working area. Foley and Zdeblick thus do not provide any motivation or suggestion for modifying their devices, and actually appear to teach away from the combination with Ash. Ash does not provide any motivation or suggestion for modifying Foley or Zdeblick. As discussed above, Foley already teaches an unexpandable device that provides the desired visualization of the working area and the ability to perform various procedures through the device. Foley thus teaches away from any combination with Ash. None of the references thus provide any motivation or suggestion for modifying the device of Foley to have an expanding region. As the Examiner has provided no articulated reasoning with any rational underpinning to support the conclusory statement of obviousness, Appellants submit the rejection is made in error.

Further, while Zdeblick does teach passing an implant through the fixed diameter sleeve 76, Zdeblick does not appear to teach or suggest the sleeve 76 is configured for passing fasteners through it. Zdeblick teaches the fusion device as having offset screw bores 267 and teaches the longitudinal axes of the two screw bores intersect outside the hollow body 251 and the end wall 256. See column 10, lines 2-9 and FIG. 10. Comparing the positioning of the screws relative to the implant in FIG. 10 with the fixed diameter sleeve 76 and implant in FIG. 11c, one of ordinary skill in the art would understand that the sleeve 76 of Zdeblick is not structured to have a cross-sectional area sized to permit visualization of two fasteners fixed to two adjacent vertebrae, as is recited in the claims. Ash does not appear to teach a device that, when expanded, is structured to permit visualization of two fasteners fixed to two adjacent vertebrae. Further, there is no motivation for one of ordinary skill in the art to modify the devices of Foley, Ash, or Zdeblick to achieve the structure of the expandable access device as claimed.

Application Serial No. 10/972,987
Appeal Brief

The Examiner asserts that he believes the combination of Foley, Ash, and Zdeblick is capable of providing simultaneous viewing of two fasteners fixed to two adjacent vertebrae. Appellants submit that there is no basis for such an assertion. The Examiner has not provided any indication of where in any of the references that such a structure is taught or suggested. Foley appears to teach a device that provides visualization of a limited region as shown in FIGS. 10a-10i. Zdeblick appears to teach a device that provides access to the interbody space between two vertebrae (FIG. 11c), but does not appear to provide visualization of two fasteners fixed to two adjacent vertebrae. Further, there is no motivation for one of ordinary skill in the art to modify the devices of Foley and Zdeblick to achieve the claimed structure because each teaches their devices as providing the necessary visualization and working area for their respective procedures. Ash does not appear to provide what Foley and Zdeblick lack. Ash appears to teach a device in which optical elements make up a majority of the space in the device compared to the access channel for instruments. For example, Ash discloses FIG. 6 having visualization elements including viewing conduit 124, light transmitting fiber 136, laser light transmitting fiber 192, and fluid tube 196. As can be seen, these elements take up a significant amount of space in the internal conduit 134 compared to the access channel 188, through which surgical elements are passed. See page 10, lines 2-28 and FIG. 6. Appellants submit that Ash does not appear to teach their device as providing the claimed structure of an elongate body having a passage sized to permit passage of at least two fasteners and a fixation element therethrough, or with a cross-section sized to permit visualization of two fasteners fixed to two adjacent vertebrae. It appears the Examiner has merely collected what are asserted as the elements of the claim without any reasoning as to why one of ordinary skill would be motivated to make the asserted combination. The Examiner has failed to provide the necessary articulated reasoning with any rational underpinning to support the conclusory statement of obviousness.

Application Serial No. 10/972,987
Appeal Brief

B. Conclusion.

For the reasons stated above, the rejection of claims 50-53 under 35 U.S.C. § 112, first paragraph, the rejection of claims 18-23, 25-27, 30-36, 38-41 and 46-48 under 35 U.S.C. § 103(a), should be reversed.

Respectfully Submitted,


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Dated: June 9, 2008

Application Serial No. 10/972,987
Appeal Brief

VIII. CLAIMS APPENDIX

18. A system for performing a fixation procedure at a spinal location within a patient, comprising:

at least two fasteners adapted to be fixed to two adjacent vertebrae;

an elongate body having a proximal end and a distal end and defining a length between the proximal and distal ends such that the proximal end can be positioned outside the patient and the distal end can be positioned inside the patient adjacent the spinal location, the elongate body including a passage extending between the proximal and distal ends sized to permit passage of the at least two fasteners therethrough; and

a fixation element sized to pass through the passage of the elongate body and configured to engage the at least two fasteners;

wherein the elongate body is actuatable between a first configuration sized for insertion into the patient and a second configuration wherein the cross-sectional area of said passage at a first location is greater than the cross-sectional area of said passage at a second location, wherein the first location is distal to the second location; wherein the cross-sectional area of said passage at said first location is sized to permit visualization of two fasteners fixed to two adjacent vertebrae.

19. The system of Claim 18, wherein the first location is at the distal end of the elongate body.

20. The system of Claim 18, wherein a distal portion of the elongate body is expandable.

21. The system of Claim 18, wherein the elongate body comprises a first tubular portion and a second expandable portion.

22. The system of Claim 18, wherein the at least two fasteners are threaded.

Application Serial No. 10/972,987
Appeal Brief

23. The system of Claim 18, wherein the at least two fasteners comprise pedicle screws.

25. The system of Claim 18, wherein the fixation element comprises a rod.

26. The system of Claim 18, further comprising an endoscope adapted to be held relative to the elongate body.

27. A system for performing a fixation procedure at or near the spine of a patient, said system comprising:

an access device adapted to define a passage from a location outside of the patient to a location at or near the spine of the patient, the access device being at least partially actuatable between a first configuration and a second configuration, wherein the passage of the access device in the second configuration has a cross-sectional area at a first location that is greater than the cross-sectional area of said passage at a second location, wherein the first location is distal to the second location; and

a vertebral fixation assembly configured to fix two adjacent vertebrae, the vertebral fixation assembly adapted to be delivered through the passage of the access device, the vertebral fixation assembly comprising a plurality of vertebral screws and a fastener adapted to engage each of the vertebral screws;

wherein the cross-sectional area at the first location is sized to permit visualization of two or more screws fixed to at least two adjacent vertebrae.

30. The system of Claim 27, wherein the fastener is a rod.

31. The system of Claim 27, further comprising a viewing device adapted to be held relative to the access device.

Application Serial No. 10/972,987
Appeal Brief

32. The system of Claim 27, wherein the access device includes a distal portion that is expandable.

33. A system for performing a fixation procedure at a spinal location within a patient, said device comprising:

an access device having a proximal end and a distal end and a length defined between the proximal and distal ends such that the proximal end can be positioned outside the patient and the distal end can be positioned inside the patient adjacent the spinal location, wherein the access device includes a passage extending there through, the access device being expandable from a first configuration to a second configuration, wherein the passage of the access device in the second configuration has a cross-sectional area at the distal end of the device that is greater than a cross-sectional area at the proximal end of the device, said passage being sized for delivery of instruments to perform the procedure at the spinal location;

at least two threaded fasteners sized for delivery through said passage at least when the access device is in its second configuration, the fasteners being configured to be fixed to adjacent vertebrae, wherein said cross-sectional area at the distal end of the device in the second configuration is sized to permit visualization of the at least two threaded fasteners fixed to at least two adjacent vertebrae; and

a fixation element sized for delivery through the passage of the access device.

34. The system of Claim 33, wherein the shape of the access device when expanded is at least partially conical.

35. The system of Claim 33, wherein the access device comprises a first tubular portion and a second expandable portion.

36. The system of Claim 33, wherein the at least two threaded fasteners comprise

Application Serial No. 10/972,987
Appeal Brief

pedicle screws.

38. The system of Claim 33, wherein the fixation element comprises a rod adapted to engage said at least two threaded fasteners.

39. The system of Claim 33, further comprising a locking member adapted to hold the fixation element relative to the threaded fasteners.

40. The system of Claim 33, wherein the threaded fasteners include a convex engagement surface at a proximal end thereof.

41. The system of Claim 40, further comprising a washer adapted to engage the convex engagement surface of the threaded fasteners.

46. The system of Claim 18, wherein the elongate body defines a substantially enclosed passage at least in its reduced configuration.

47. The system of Claim 27, wherein the access device defines a circular cross-section at least in its reduced configuration.

48. The system of Claim 33, wherein the access device defines a circular cross-section at least in its reduced configuration.

Application Serial No. 10/972,987
Appeal Brief

IX. EVIDENCE APPENDIX

No additional evidence has been presented.

Application Serial No. 10/972,987
Appeal Brief

X: RELATED PROCEEDINGS APPENDIX

There are no related appeals or interferences.